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# Form Approved REPORT DOCUMENTATION PAGE OMB No. 0704-0188 Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS. 1. REPORT DATE (DD-MM-YYYY) 2. REPORT TYPE 3. DATES COVERED (From - To) 01-05-2006 Final 15 Apr 2002 - 14 Apr 2006 4. TITLE AND SUBTITLE 5a. CONTRACT NUMBER Preventing Overweight in USAF Personnel: A Minimal Contact Program. **5b. GRANT NUMBER** DAMD17-02-1-0180 **5c. PROGRAM ELEMENT NUMBER** 6. AUTHOR(S) 5d. PROJECT NUMBER John P. Foreyt, Ph.D. 5e. TASK NUMBER 5f. WORK UNIT NUMBER E-Mail: jforeyt@bcm.tmc.edu 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 8. PERFORMING ORGANIZATION REPORT NUMBER **Baylor College of Medicine** Houston, TX 77030 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. SPONSOR/MONITOR'S ACRONYM(S) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 11. SPONSOR/MONITOR'S REPORT NUMBER(S) 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 13. SUPPLEMENTARY NOTES 14. ABSTRACT: The research objective of this 4-year study was to evaluate the effectiveness of a minimal contact Internet-base behavioral therapy plus usual care (MCBT + UC) for controlling overweight in the USAF personnel using a controlled experimental comparison of usual care (UC). Subject included personnel who are 5 lbs below their Maximum Allowable Weight (MAW) and heavier. Effectiveness of MCBT + UC was compared to UC in terms of weight loss. Outcomes were measured at 6 months and 12 months. A total of 451 subjects were recruited (227 in treatment groups and 225 in usual care group). All follow-up assessments were completed in November 2005. Results compare baseline, 6-month, and 12-month outcome found that subjects assigned to MCBT lost weight while those assigned to UC actually gained weight. Also, greater use of the treatment website was associated with significantly more weight loss over the 6-month treatment period. 15. SUBJECT TERMS Obesity, Behavior Modification, Fitness, Diet, Weight 16. SECURITY CLASSIFICATION OF: 17. LIMITATION 18. NUMBER 19a. NAME OF RESPONSIBLE PERSON

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### INTRODUCTION:

Maintaining healthy body weight is a critical part of readiness in the United States Air Force (USAF). The USAF has not escaped the same weight management problems that the US civilian population is experiencing. Therefore, the need for improving existing weight programs currently available to the USAF is of great importance and part of the mission of this study. The research objective of this study was to evaluate the effectiveness of a minimal contact behavioral therapy plus usual care (MCBT + UC) for controlling overweight in the USAF personnel using a controlled experimental comparison of usual care (UC). Subjects included active duty personnel who are 5 lbs. below their Maximum Allowable Weight (MAW) and heavier. Effectiveness of MCBT + UC was compared to UC in terms of weight loss. Outcomes were measured at 6 and 12 months. The ultimate goal of this study is to provide an effective and easily disseminable weight management treatment to any interested military installation.

#### BODY:

### **YEAR 1 (15 April 2002 – 14 April 2003):**

Project coordinator, Lisa Alvarez, and research associate, Antoinette Brundige, were hired in August 2002. Various administrative tasks were completed including the ordering of all research materials and all assessment measures/licenses.

The training of project staff in Motivational Interviewing was conducted with the inclusion of didactics, readings, training videos, and practice sessions as well as a training seminar. In addition, the telephone scripts for the Motivational Interviews were developed.

The complete website platform was developed including the 24 weeks of military related weight and exercise content and the online databases for data entry/management. The website was pilot tested and all aspects, including the food/exercise diaries and data entry, were fully functioning. Data entry/management procedures were established including coding and a double entry checking system for quality assurance.

Plans for data flow, recruiting, randomization and treatment were coordinated between all study personnel and a schedule for quarterly updates between all personnel was established. Plans were coordinated for recruitment between grant personnel and the three Health and Wellness Centers (HAWCs).

### **YEAR 2 (15 April 2003 – 14 April 2004):**

Recruitment began in June 2003 at Lackland AFB and in July 2003 at both Brooks City Base and Randolph AFB.

Due to a change in Air Force policy regarding weight and fitness in January 2004, modifications to recruitment methods for this study were required and a number of new recruitment methods were added to the original protocol, all such methods were IRB approved prior to implementation. These methods focused on the development and distribution of informational flyers used in both an electronic and paper format. These flyers were our primary means of recruitment.

A second research associate, Jodi Atkinson, was hired in June 2003. The website including the 24 weekly lessons and food/exercise/weight diaries were fully functioning and being used by treatment subjects; online databases used for data management were also fully functioning; data entry/management procedures for quality assurance including coding and a double entry checking system were being utilized by research staff.

During year 2, approximately 60 subjects completed the treatment program. Six-month follow-up assessments began in January 2004.

# **YEAR 3 (15 April 2004 – 14 April 2005):**

Twelve-month follow up assessments began in June 2004. The final orientation session for the study's treatment program was conducted in November 2004.

Recruitment ended at the three HAWC sites in October 2004 with a total of 451 subjects. The total number of participants recruited is less than the number proposed in the original protocol. Changes in Air Force mission and policy played a major role in recruitment difficulties. The new policy impacted our recruitment in two significant ways: the elimination of a mandatory Maximum Allowable Weight (MAW) for Active Duty personnel and the elimination of the position of Fitness Assessment Monitor (FAM), our primary means of recruitment. We also experienced problems enrolling subjects at one recruitment site in particular. It was initially projected that we would recruit approximately 30% of participants from Brooks City Base. Only 4% of study participants were recruited from this site despite equal effort given in terms of recruitment briefings, etc. Initial projections overestimated our recruitment potential at this site. Brooks City Base has the smallest population of Active Duty personnel of the 3 recruitment sites.

## **YEAR 4 (15 April 2005 – 14 April 2006) FINAL YEAR:**

The following is a list of personnel who received pay from the research effort:

John P. Foreyt, Ph.D.
David Van Brunt, Ph.D.
Christopher K. Haddock, Ph.D.
Walker S.C. Poston, Ph.D.
Lisa M. Alvarez, Ph.D.
Antoinette Brundige, M.A.
Jodi Atkinson, M.A.
Sharon Griggs

Six-month follow up assessments were completed in May 2005. Twelve-month follow up assessments were completed in November 2005.

All data entry was completed and final data analysis has been conducted.

**Results**: (See Supporting Data for Tables and Figures)

#### Statistical Analysis

Statistical analyses were performed using SPSS® (version 13.0; SPSS Inc., Chicago, IL, USA). Means ± standard deviation scores or percentages were calculated for all baseline demographic variables. We used repeated measures ANOVA to examine 6- and 12-month changes from baseline in weight (kg), BMI, body fat percentage, waist and circumference using both completers and intention-to-treat using the last observation carried forward (LOCF), as recommended by CONSORT Guidelines (2001). We also used repeated measures ANOVA to examine changes in diet and physical activity on completers only because these were secondary outcomes. We used MANCOVA to examine differences on the WEL and the IWQOL by using the 6- and 12-month change scores as the dependent variable and adjusting for baseline scores for completers only, also because these were secondary outcomes.

To evaluate predictors of significant weight loss after the 6-month active treatment period among those receiving the MCBIT intervention, we divided weight loss into quartiles and dichotomized the variable into the highest quartile of weight loss vs. all other quartiles. We then developed a multivariate logistic regression model to identify factors related to being classified in the highest quartile of weight loss. We used the model building approach proposed by Hosmer and Lemeshow (2000); a priori selection of variables was based on theoretical and empirical

relevance. All potential predictors were first force entered into the model. Variables with the least explanatory power and with p-values greater than 0.10 were eliminated from the model.

#### Intervention Fidelity Check

We first examined several process variables to ensure that the MCBIT intervention was delivered to participants assigned to the treatment group. First, we calculated the frequency of receiving the motivational phone calls during the treatment period and found that 93.4% of treated participants were available for the 4-week motivational phone call and 78.4% received the 8-week call. Next, we examined website use by participant self-report and total actual website logins. Participants reported their website use as less than once per week (42.4%), 1-2 (22.6%), 3-4 (18.1%), 5-7 (9.6%), and 7+ (7.3%) times per week, respectively. MCBIT treated participants logged into the website an average of 49.1(83.3) times over the treatment period, with a range of 1-707 logins. We then converted the actual logins into quartiles of use and found the following distribution of total logins: Quartile  $1 = 3.8 \pm 2.5$  logins; Quartile  $2 = 15.6 \pm 4.0$  logins; Quartile  $3 = 35.4 \pm 8.8$  logins; and Quartile  $4 = 133.6 \pm 83.7$  logins.

We examined the relationship between weight loss and self-reported website use and actual logins among those assigned to receive the MCBIT intervention. Table 2 presents the correlations and significance levels. There was a statistically significant and modest relationship between both self-reported website use, actual login frequency, and weight loss, indicating that greater use of the website by either metric was associated with significantly more weight loss over the 6 month treatment period. In addition, Figure 1 presents weight losses (kg) by category of self-reported use and by actual login quartile among MCBIT participants. Treated participants generally lost more weight with greater use of the site regardless of metric (i.e., self-reported weekly use or total actual logins)

# Changes in Body Composition

Table 3 presents changes in body composition by treatment assignment at the end of treatment (6 months). Participants assigned to the MCBIT intervention lost  $-1.3\pm4.1$ kg while those assigned to usual care actually gained  $0.6\pm3.4$ kg and this difference was statistically significant using RANOVA (F = 24.17; p<0.001). Results were similar when using in LOCF model, with participants who received the MCBIT intervention losing  $-1.0\pm3.7$ kg while those in usual care gained  $0.5\pm3.1$ kg (F = 23.12; p=0.001). Changes in the other body composition outcomes, i.e., BMI, waist circumference, and body fat percentage also are presented in Table 3. MCBIT treated participants experienced significantly greater favorable body composition changes on all measures (p<0.001 for all). Table 4 presents completers weight loss data stratified by BMI level, MAW status, and gender.

Weight loss differences between MCBIT and usual care were significant in all stratified analyses (p<0.01). However, there were no significant interactions between treatment group assignment and BMI level, MAW status, or gender indicating that none of these factors significantly moderated the effects of the MCBIT intervention.

Table 5 presents change in outcomes from baseline to 12 months (6 months after treatment termination). Participants assigned to the MCBIT intervention demonstrated a net loss of -  $0.1\pm4.4$ kg from their baseline weight at 12 months while those assigned to usual care gained  $1.0\pm4.2$ kg and this difference was statistically significant using RANOVA (F = 5.35; p = 0.021). Twelve months results were similar when using in LOCF model, with participants who received the MCBIT intervention losing - $0.3\pm4.3$ kg while those in usual care gained  $1.0\pm4.0$ kg (F = 10.68; p = 0.001). Twelve months changes in the other body composition outcomes, i.e., BMI,

waist circumference, and body fat percentage also are presented in Table 5. MCBIT treated participants experienced significantly greater favorable body composition changes only in BMI change at 12 months (F = 5.14; p = 0.024). None of the other body composition measures were significantly different between MCBIT and usual care.

Significantly more treated participants met the 5% or more weight loss criterion at 6 months, with 22.6% losing at least 5% of initial body weight compared to only 6.8% of usual care participants ( $X^2 = 18.59$ ; p<0.001). This effect remained at 12 months (i.e., 6 months after treatment termination) with 16.8% and 9.4% of MCBIT and usual care participants ( $X^2 = 3.96$ ; p = 0.047), respectively, still meeting the 5% or more weight loss criterion. Because the focus on this intervention was on prevention of weight gain, we also classified participants according to whether they maintained or lost weight during the intervention period compared to those who gained any weight. Participants receiving the MCBIT intervention were significantly less likely to be classified as weight gainers (41.8%) at the 6-month assessment when compared to those in the usual care condition (59.7%;  $X^2 = 11.75$ ; p = 0.001). At 12 months, this effect was still significant with 48.4% of MCBIT and 61.8% of those in usual care gaining any weight ( $X^2 = 5.93$ ; p = 0.015)

There were no significant differences in follow-up at 6 months across groups, with an overall attrition rate of 21.0% for the internet-treated group and 14.0% for those in usual care ( $X^2 = 3.81$ ; p=0.051) with an overall dropout rate of 17.1%. Those that dropped out were somewhat younger (32.4±7.8 vs. 34.3±7.2; F = 4.37, p = 0.037) and slightly heavier (30.14±3.4 vs. 29.2±2.8; F = 5.78, p = 0.017). Attrition at 12 months increased slightly to 28.1% among MCBIT participants and 23.4% among those in usual care ( $X^2 = 1.29$ ; p = 0.256)

# Changes in Diet and Physical Activity

We examined changes in the primary scales of the Block Rapid Food Screener to Assess Fat and Fruit and Vegetable Intake (Block et al., 2000). Significant group by time interactions were found for both the Meat and Snacks Screener Score (F = 4.034; p = 0.045) and the Fruit-Vegetable-Beans Screener Score (F = 9.921; p = 0.002). Mean changes scores for both the MCBIT and usual care groups are provided in Table 3. Finally, we used the IPAQ to evaluate changes in physical activity levels. We examined changes in total MET-minutes/week and found no significant differences between MCBIT and usual care participants in physical activity change (F = 0.036; p = 0.850).

### Changes in Weight Efficacy and Quality of Life

Because subscales on the WEL (r = 0.540-0.718; p<0.001) and IWQOL (r = 0.246-0.582; p<0.001) were so highly correlated within each measure, we examined change scores for each scale. These analyses included adjustments for each baseline subscale for each measure using MANOVA to test for group differences between participants receiving MCBIT vs. usual care. Tables 3 and 5 provide the change scores on both measures for completers. Completer's analyses only were conducted on these measures because they were secondary outcomes.

The overall MANOVA for the WEL was significant (F = 2.604; p = 0.025) at 6 months. Significant differences between participants assigned to MCBIT and usual care were found on some of the WEL scales at 6 months. Post-hoc analyses demonstrated that MCBIT participants demonstrated significant increases on the WEL Social Pressure (F = 3.931; p = 0.048), WEL Positives Activities (F = 10.260; p = 0.001) and WEL Availability (F = 4.340; p = 0.038) relative to those receiving usual care only. No significant differences were demonstrated on the IWOOL

scales for the overall MANOVA (F = 1.943; p=0.087). No significant group differences were found for the IWQOL at 6-months or for either measure at 12-months.

# Predictors of Weight Loss among MCBIT Participants

In order to determine which participants in the MCBIT condition benefited most from the treatment and because there was wide variation in the amount of weight maintenance and loss among MCBIT participants we stratified MCBIT participants into quartiles of weight loss with the highest quartile losing an average of -5.4±2.8kg. We then examined baseline demographic and clinical variables that might theoretically contribute to successful weight loss including age, gender, marital and education status, race, years of service in the USAF, baseline BMI, baseline physical activity level, baseline scores on the WEL scales (as measures of baseline self-efficacy for weight loss), and how frequently they used the website (i.e., number of logins) during the intervention period.

The logistic regression model predicting membership in the highest quartile of weight loss among MCBIT participants was statistically significant (Chi-square = 38.0604; p < 0.001) and showed good fit to the data (Hosmer and Lemeshow Test, Chi-square = 8.219; p = 0.412). Variables that remained in the model were website login frequency in quartiles (p<0.001; the lowest quartile of use was the reference group) with the participants in the second, third, and fourth quartiles being 3.4 (95%CI = 0.7-18.2), 4.7 (95%CI = 0.9-23.9), and 16.7 (95%CI = 3.4-82.6) times more likely to be in the highest quartile of weight loss. In addition, higher scores on the WEL Negative Emotions scale (OR = 1.1; 95%CI = 1.050-1.198) and lower scores on the WEL Social Pressure scale (OR = 0.91; 95%CI = 0.854-0.979) were associated with a greater chance of being in the highest quartile of weight loss.

#### KEY RESEARCH ACCOMPLISHMENTS:

 Results comparing baseline, 6-month, and 12-month outcomes found that subjects assigned to MCBT lost weight while those assigned to UC actually gained weight.

#### **REPORTABLE OUTCOMES:**

**Publications:** None to date: Main paper and several ancillary papers in preparation.

### **Presentations:**

Hunter, C. (November, 2004) <u>Weight Management Issues in the Military</u>. Invited presentation to the North American Association for the Study of Obesity (NAASO) Annual Scientific Meeting, Las Vegas, Nevada. - For Abstract, see Appendix 1

Hunter, C. and Foreyt, J. (October, 2005). <u>Weight Management in U.S. Military Personnel:</u> <u>Interactive Intervention.</u> Invited presentation at the 2005 North American Association for the Study of Obesity, Vancouver, Canada. – For Abstract, see Appendix 2

Poston, W.S.C., & Hunter, C. (December, 2005). <u>Internet based weight management in the military</u>. Invited presentation at the 2005 Pennington Scientific Symposium on Prevention of Weight Gain and Weight Regain, Pennington Biomedical Research Center, The Louisiana State University, Baton Rouge, Louisiana. – For Abstract, see Appendix 3

#### **CONCLUSION:**

The prevalence of overweight and obesity in the U.S. Air Force (USAF) is 62%. Each year women in the Air Force gain 1.3 pounds and men gain 1.9 pounds. Weigh gain prevention efforts in the Air Force have been poorly studied and had minimal effect. Further, intensive individualized weight loss programs are expensive and have many barriers to attendance, so a minimal contact approach holds promise. This study tested the effectiveness of Minimal Contact Behavioral Internet Therapy plus usual care (MCBIT) compared to usual care (UC) in a randomized trial. Results comparing baseline to 6-month outcomes found that subjects assigned to the MCBIT condition had a significant weight loss while those assigned to usual care UC actually gained weight. Comparing the maintenance phase, from 6 months to 12-month outcomes, the MCBIT condition maintained a significantly greater weight loss as compared to UC; whose weight gain trajectory continued upwards. The efficacy of a minimal contact/flexible Internet intervention for prevention of weight gain and weight loss is critically important to the military given the operations tempo and the health and readiness impact of excess weight in the military.

#### REFERENCES:

Moher, D., Schulz, K.F., & Altman, D. (2001). The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomized Trials. *JAMA*, 15, 1987-1991.

#### APPENDIX 1:

Hunter, C. (November, 2004) <u>Weight Management Issues in the Military</u>. Invited presentation to the North American Association for the Study of Obesity (NAASO) Annual Scientific Meeting. Presentation, Las Vegas, Nevada.

# Minimal Contact Intervention to Weight Loss and Weight Gain Prevention: A Population Health Approach

Maintaining healthy body weight is a critical part of readiness in the United States Air Force (USAF). The prevalence of overweight and obesity in the USAF is about 62% (53% BMI\geq 25, 8% BMI\geq 30). On average active duty members gain 1.3-2 lbs a year and the prevalence of overweight has increased 3 to 4% over the last 5 years, reflecting trends in the civilian population. Although, behavioral weight loss treatments are effective, intensive in-person implementation of such treatments is expensive and many active duty personnel have limited time resources for attendance. A population health approach targeting all overweight personnel as well as those at risk, using a flexible minimal contact approach may be the most effective way to control prevalence of overweight.

This study compares the effectiveness of a minimal contact behavioral therapy plus usual care (MCBT + UC) using a controlled experimental comparison of usual care (UC). The total sample will include 1200 Active Duty personnel who are 5lbs below their Maximum Allowable Weight (MAW) and heavier. MCBT + UC will include provision of the LEARN manual as a self-help tool, use of an interactive weight management web site for 24 weeks, and 2 brief motivational interviewing telephone follow-ups, plus usual care. Treatment duration is 6 months. UC consists of the USAF required annual physical exam and fitness test with a requirement to stay below a Maximum Allowable Weight (MAW), along with any mandatory or self-selected weight loss methods. Effectiveness of MCBT + UC will also be compared to UC in terms of percentage of participants who are below their MAW. Outcomes will be measured at 6 and 12 months.

This study was designed to allow a population level approach to recruitment and intervention. Presentation will include description of innovative on-line program design, recruitment procedures and findings with the first 75 subjects in regard to recruitment and preliminary outcome data.

#### **APPENDIX 2:**

Hunter, C. and Foreyt, J. (October, 2005). <u>Weight Management in U.S. Military</u> <u>Personnel: Interactive Internet Intervention</u>. Invited presentation at the 2005 North American Association for the Study of Obesity, Vancouver, Canada.

Randomized Trial of an Interactive Internet Weight Loss Program: Six-Month Results

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Eli Lilly

The prevalence of overweight/obesity in the U.S. Air Force (USAF) is 62% and has increased 3-4% each year for the last 5 years. Intensive face-to-face weight loss programs are expensive and have many barriers to attendance, so a minimal contact approach holds promise. This study tested the effectiveness of Minimal Contact Behavioral Internet Therapy plus usual care (MCBIT) compared to usual care (UC) in a randomized trial. MCBIT included 24-weeks of an interactive Internet weight loss program, a self-help book, and 2 motivational interviewing phone calls. UC consisted of any mandatory or self-selected weight loss methods. The sample included 451 USAF personnel who were 5lbs below their Maximum Allowable Weight (MAW) and heavier. Participants mean age was 33.9 (SD=7.3) years, 50% were men, mean BMI was 29.4(SD=3.0), and ethnic representation was 55% Caucasian, 23% African American, 16% Hispanic, and 6% others. Participants in MCBIT, above MAW, lost 1.2±4.0kg while those assigned to UC gained 0.5±3.5kg (Wilk's Lamda=15.66; p<0.001). In the below MAW group, MCBIT participants lost 2.7±4.4kg while those in UC gained 1.0±2.3kg (Wilk's Lamda=13.27; p=0.001). Treated participants experienced significantly more favorable body composition changes (waist circumference and body fat) on all measures (p<0.01 for all) except for body fat in the below MAW group (p=0.074). Significantly more treated participants met the 5% or more weight loss criterion, regardless of MAW status. Among the above MAW group, 23.2% lost at least 5% of initial body weight compared to only 7.4% of UC participants (p<0.001). Among below MAW participants, more MCBIT (20.0%) than UC (4.0%) met the criterion, but the difference was not significant (p=0.090). There was a significant relationship between website use and weight loss. The efficacy of a minimal contact Internet intervention is critically important given the health and readiness impact of excess weight in the military.

#### APPENDIX 3:

Poston, W.S.C., & Hunter, C. (December, 2005). <u>Internet based weight management in the military</u>. Invited presentation at the 2005 Pennington Scientific Symposium on Prevention of Weight Gain and Weight Regain, Pennington Biomedical Research Center, The Louisiana State University, Baton Rouge, Louisiana.

# Controlled Trial of an Interactive Internet Weight Loss Program: Six- and Twelve-Month Outcomes

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National surveys document that rates of overweight and obesity have increased steadily among adults over the last 40 years in the United States. The U.S. military also has experienced substantial increases in overweight and obese personnel despite an emphasis on fitness and readiness. For example, Bray and colleagues reported that the prevalence of overweight among active duty military personnel in 1995 was 49.0%, increasing to 57.2% by 2002. The prevalence of overweight and obesity in the U.S. Air Force (USAF) is 60% with small but steady increases each year.. This trend raises concerns about the potential health and financial impacts on the military. For example, health care costs attributable to excess bodyweight for the USAF exceeded \$22.8 billion per year and represents 5.6% of total medical care expenditures. Productivity also was negatively impacted, with an estimated 28,351 lost workdays resulting in \$3.5 million dollars in productivity losses. However, greater discharge risk and associated costs have not been demonstrated. Within this context, military weight and fitness management programs were developed for all services and were designed to ensure that active duty personnel are able to meet the physical demands of their duties. Failure to meet established service ageand sex-adjusted standards could result in significant career disruption, including unfavorable administrative actions, withholding of promotions, and involuntary discharge or separation.

Because of the potential negative associations and stigma that many active duty USAF personnel have toward publicly seeking help for weight loss, and because intensive individualized weight loss programs are expensive and have many barriers to attendance, we developed a minimal contact approach that incorporated the internet for weight loss and weight gain prevention. Internet interventions have been demonstrated to be effective for inducing weight loss in several randomized trials. However, they have not been studied in military populations. Since most active duty USAF members have access to the internet, they serve a particularly viable population to test an adapted internet intervention. Our study evaluated the effectiveness of this Minimal Contact Behavioral Internet Therapy plus usual care (MCBIT) compared to usual care (UC) in a 6-month randomized trial. MCBIT included 24-weeks of an interactive Internet weight loss program, a self-help book, and 2 motivational interviewing telephone calls. UC consisted of any mandatory or self-selected weight loss methods.

The sample included 446 USAF personnel (n = 224 MCBIT, n = 222, UC) with BMIs  $\geq$  24. Participants randomized the MCBIT and UC groups mean age was 33.5 $\pm$ 7.4 and 34.4 $\pm$ 7.2 years. Both groups had 50% men. Ethnic representation was 55% Caucasian, 23% African American, 16% Hispanic, and 6% others. There were no significant differences in demographic or clinical factors at baseline. Participants assigned to the MCBIT intervention lost -1.3 $\pm$ 4.1kg while those assigned to UC actually gained 0.6 $\pm$ 3.4kg and this difference was statistically significant using RANOVA (Wilk's Lamda = 24.17; p<0.001). Thus, the absolute weight

difference at 6 months was 1.9kg. Results were similar when using in LOCF model, with participants who received the MCBIT losing -1.0±3.7kg while those in UC gained 0.5±3.1kg (Wilk's Lamda = 23.12; p=0.001). Treated participants also experienced significantly greater favorable body composition changes (e.g., BMI, waist circumference, and body fat percentage; p<0.001 for all). Significantly more treated participants met the 5% or more weight loss criterion, with 22.6% losing at least 5% of initial body weight compared to only 6.8% of usual care participants (p<0.001). No significant differences in follow-up at 6 months across groups, with an overall attrition rate of 21.0% for the internet-treated group and 14.0% for those in usual care with an overall dropout rate of 17.1% (p=0.061). At the 12-month assessment of weight loss maintenance or weight gain prevention (6 months after treatment termination), we assessed how well participants maintained their weight changes. Those who received the MCBIT program still weighed less than their baseline weight (-0.13±4.4kg) while those in UC gained additional weight 1.00±4.2kg and this difference was statistically significant (Wilk's Lamda = 5.71; p=0.017). The absolute weight difference at 12 months was 1.13kg. In addition, significantly more treated participants continued to meet the 5% or more weight loss criterion, with 16.9% losing at least 5% of initial body weight compared to only 9.5% of UC participants (p<0.046).

Because a focus of this study was weight gain prevention, another way to examine weight changes would be to determine the percentage of participants who maintained or lost weight vs. those who gained weight at both 6 and 12 months. At 6 months, 58.2% of MCBIT participants maintained or lost weight vs. 40.3% of UC patients (p = 0.001). By 12 months, 51.2% maintained or lost weight vs. only 37.9% of UC patients (p = 0.011). Thus, the MCBIT intervention appeared to be successful for preventing weight gain and inducing weight loss. The efficacy of minimal contact/flexible Internet intervention is critically important given the health and readiness impact of excess weight in the military.

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# SUPPORTING DATA: Table and figures

Table 1. Participant Characteristics by Treatment Status

Characteristic*	MCBIT	Usual Care	p-value
N	224	222	
Age (yrs)	33.5±7.4	34.4±7.2	0.224
Gender (% Female)	50.0	50.5	0.924
Ethnicity (% Caucasian)	58.0	53.2	0.398
Marital Status (% Married or partnered)	70.1	73.0	0.780
Percent Enlisted (%)	81.7	75.2	0.061
Years of Service (yrs)	12.4±6.6	13.0±6.6	0.394
Plan to retire from AF (% yes)	78.9	81.4	0.771
Education (% HS or some college)	63.9	61.7	0.757
BMI (kg/m²)	29.4±3.0	29.3±3.0	0.671
Weight (kg)	87.4±15.6	86.6±14.7	0.576
Waist Circumference (cm)	94.5±11.0	94.2±10.9	0.784
Body Fat (%)	34.5±6.8	34.2±6.9	0.649
Block Dietary Screener			
Meat and Snacks Screener Score	23.6±7.9	24.2±8.0	0.416
Percent of Calories from Fat	35.1±4.8	35.5±4.9	0.411
Fruit-Vegetable-Beans Screener Score	13.7±5.5	14.2±5.8	0.364
Dietary Fiber Score	15.8±4.5	16.1±4.8	0.442
IPAQ (Total MET-minutes/week)	2787.7±2863.0	2671.5±3113.7	0.697
Weight Efficacy Lifestyle (WEL) Questionnaire			
Negative Emotions	23.9±8.6	24.2±8.4	0.675
Social Pressure	24.7±7.6	24.8±7.0	0.910
Physical Discomfort	27.6±6.2	28.7±5.3	0.050
Positive Activities	25.8±6.8	26.0±6.5	0.708
Availability	19.8±7.7	19.5±7.8	0.624
Impact of Weight on Quality of Life (IWQOL)			
Physical Functioning	17.4±5.9	18.1±6.6	0.272
Self-Esteem	18.4±7.7	18.7±7.7	0.748
Sexual Life	6.4±3.6	6.4±3.7	0.940
Physical Distress	6.0±1.9	6.1±2.0	0.479

Table 2. Intervention Fidelity Check Among Treated Participants During the 6-Month Active Treatment Period

	Number of Logins From Site Counter	Self-Reported Logins
Self-Reported Logins	0.562(<0.001)	::
6 Month Weight Change	-0.384(<0.001)	-0.395(<0.001)
6 Month BMI Change	-0.379(<0.001)	-0.393(<0.001)
6 Month Bodyfat Percent Change	-0.367(<0.001)	-0.380(<0.001)
6 Month Change in WC	-0.352(<0.001)	-0.308(<0.001)

Table 3. Change in Primary Outcomes from Baseline to 6-months (Active treatment period

only)\*

Outcomes	MCBIT	Usual Care	
Weight (kg)	-1.3±4.1	0.6±3.4	
BMI (kg/m²)	-0.5±1.4	0.2±1.1	
Waist Circumference (cm)	-2.1±4.3	-0.4±3.8	
Bodyfat Percentage	-0.4±3.1	0.6±2.9	
5% or More Weight Change (% yes)	22.6	6.8	
No follow-up 6 months (% dropout)	21.0	14.0	
Block Dietary Screener <sup>¥</sup> Meat and Snacks Screener Score Percent of Calories from Fat  Fruit-Vegetable-Beans Screener Score Dietary Fiber Score	-5.2±7.6 -3.1±4.6 2.3±5.3 1.7±3.9	-3.7±6.6 -2.2±4.0 <b>0.5±5.5</b> 0.4±4.0	
IPAQ (Total MET-minutes/week)	269.3±1986.2	312.4±1697.4	
WEL Negative Emotions Social Pressure Physical Discomfort Positive Activities Availability	1.8±6.6 2.5±6.6 1.6±5.6 2.3±5.7 3.2±7.0	1.7±7.1 1.3±7.1 0.8±5.5 0.8±5.5 2.2±7.0	
IWQOL Physical Functioning Self-Esteem Sexual Life Physical Distress Work	-2.1±5.0 -3.6±5.5 -1.0±2.8 -0.4±1.3 -0.4±1.4	-2.3±5.0 -3.3±5.6 -0.6±2.6 -0.3±1.9 -0.5±2.0	

<sup>\*</sup>Data presented for completers. Bolded differences were statistically significant. \*RANOVA models only run for main dietary screener scores.

Table 4. Primary 6-month Outcomes Stratified by BMI Level, MAW Status, Gender, and Race\*

	BMI Level	
	MCBIT	<b>Usual Care</b>
BMI < 27 (21.5%)	$-1.2 \pm 3.5$	0.9± 2.6
BMI ≥ 27 (78.5%)	-1.3 ± 4.2	0.5± 3.6
	MAW Status	
	<u>MCBIT</u>	<b>Usual Care</b>
Below MAW (12.8%)	$-2.6 \pm 4.4$	1.2± 2.3
Above MAW (87.2%)	-1.2 ± 4.0	0.5± 3.5
	Gender	
	<u>MCBIT</u>	Usual Care
Male (50.0%)	$-1.4 \pm 4.6$	0.6± 3.7
Female (50.0%)	$-1.3 \pm 3.5$	0.6± 3.0
	Race	
	MCBIT	Usual Care
Minority (45%)	$-1.0 \pm 3.8$	0.5± 3.1
Caucasian (55%)	$-1.5 \pm 4.3$	0.7± 3.6

<sup>\*</sup>Differences in weight by treatment status were significant in analyses stratified by BMI, MAW, Gender, and Race. Weight loss differences between MCBIT vs. Usual Care were significant in all stratified analyses. However, there were no significant interactions between treatment assignment and BMI level, MAW status, gender or race, but power to asses these was low (i.e., ≤ 0.50).

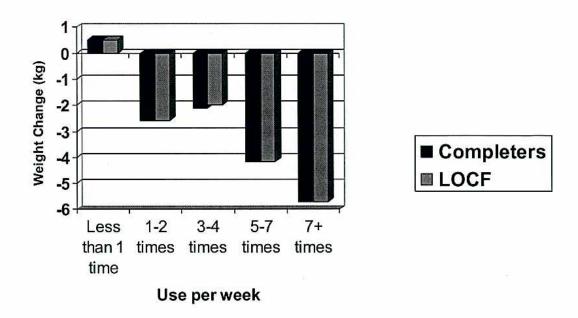
Table 5. Change in Primary Outcomes from Baseline to 12-months\*

Outcomes	MCBIT	Usual Care	
Weight (kg)	-0.1±4.4	1.0±4.2	
weight (kg)	-0.1_4.4	1.014.2	
BMI $(kg/m^2)$	-0.04±1.5	0.33±1.4	
Waist Circumference (cm)	-1.5±7.8	-0.47±8.4	
Bodyfat Percentage	-0.24±4.4	0.50±4.8	
5% or More Weight Change (% yes)	16.8	9.4	
No follow-up 12 months (% dropout)	28.1	23.4	
Block Dietary Screener*			
Meat and Snacks Screener Score	-5.2±7.3	-3.9±7.3	
Percent of Calories from Fat	-3.1±4.4	-2.3±4.4	
Fruit-Vegetable-Beans Screener Score	1.9±5.5	$0.7 \pm 5.4$	
Dietary Fiber Score	1.4±4.0	$0.6\pm4.0$	
IPAQ (Total MET-minutes/week)	149.1±1643.3	342.6±2165.6	
WEL			
Negative Emotions	3.0±6.6	1.6±5.9	
Social Pressure	2.7±6.2	$1.4 \pm 7.2$	
Physical Discomfort	$2.0\pm5.2$	$0.7\pm5.1$	
Positive Activities	2.3±5.1	$1.3 \pm 5.8$	
Availability	4.1±6.6	3.1±6.9	
IWQOL			
Physical Functioning	$-1.9\pm5.3$	$-2.4\pm5.1$	
Self-Esteem	-3.9±5.5	-3.6±5.9	
Sexual Life	$-0.7\pm2.6$	-0.8±2.9	
Physical Distress	-0.3±1.6	-0.4±1.6	
Work	$-0.4 \pm 1.8$	$-0.5\pm2.1$	

<sup>\*</sup>Data presented for completers. Bolded differences were statistically significant. \*RANOVA models only run for main dietary screener scores.

Figure 1. Weight Change After 6-Month Active Treatment Phase by Category of Self-Reported Website Use and Site Logins

# Self-Reported Site Use



# Site Use by Actual Logins in Quartiles

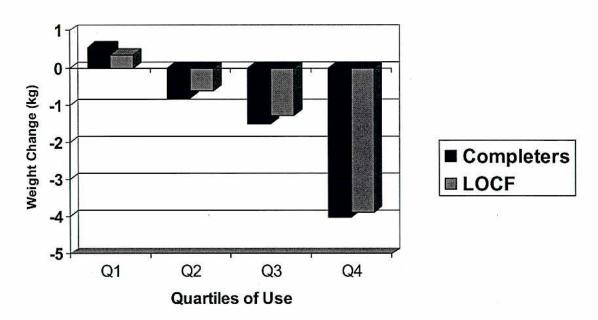


Figure 2. Weight loss (Weight Change Percent) by Treatment Status at 6 months

# Completers

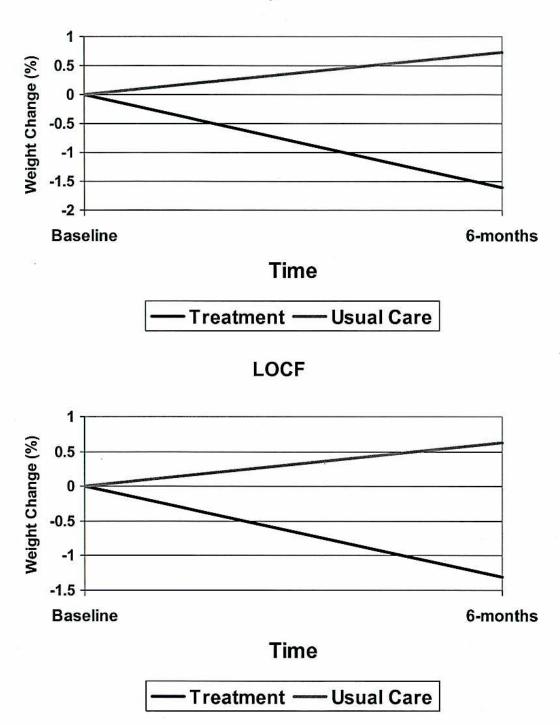


Figure 3. Weight loss (Weight Change Percent) by Treatment Status at 6- and 12-months



